

7. Bayer lacks knowledge or information sufficient to form a belief as to Plaintiff's citizenship and therefore denies the allegations in this paragraph.

8. Bayer lacks knowledge or information sufficient to form a belief as to Plaintiff's citizenship and therefore denies the allegations in this paragraph.

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69. Bayer lacks knowledge or information sufficient to form a belief as to Plaintiff's citizenship and therefore denies the allegations in this paragraph.

70. Bayer lacks knowledge or information sufficient to form a belief as to Plaintiff's citizenship and therefore denies the allegations in this paragraph.

71. Bayer admits that Bayer Corporation is incorporated in Indiana. Since 2017, Bayer Corporation's principal place of business has been in Whippany, New Jersey. Bayer also admits that Bayer Corporation was authorized to do business and did business in Pennsylvania at the time this suit began. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

72. Bayer denies that Bayer Corporation is the parent corporation and owns “100% of the Bayer subsidiaries.” Bayer also denies any and all remaining or inconsistent allegations in this paragraph.

73. Bayer Corporation is wholly owned by Bayer US Holding LP. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

74. Bayer AG is a German Aktiengesellschaft with its principal place of business in Germany. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

75. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

76. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

77. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

78. Bayer HealthCare LLC is a Delaware limited liability company whose members are NipponNex Inc., Bayer Medical Care Inc., Bayer West Coast Corporation, Bayer Essure Inc., Bayer Consumer Care Holdings LLC, Dr. Scholl’s LLC, Coppertone LLC, MiraLAX LLC and Bayer HealthCare US Funding LLC and as such, Bayer HealthCare LLC is owned by those entities. Bayer states that Bayer HealthCare LLC is a citizen of Delaware, New Jersey, Pennsylvania, Germany, and the Netherlands for purposes of diversity jurisdiction. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

79. Bayer Essure Inc. is incorporated in Delaware and has its principal place of business in Whippany, New Jersey. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

80. Bayer HealthCare Pharmaceuticals Inc. is incorporated in Delaware and has its principal place of business in Whippany, New Jersey. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

81. Bayer admits that this paragraph of the complaint invokes diversity jurisdiction under 28 U.S.C. § 1332.

82. Bayer admits that this paragraph of the complaint alleges that the amount in controversy exceeds \$75,000.

83. Bayer admits that this paragraph alleges that the parties in this matter are diverse.

84. Bayer lacks knowledge or information sufficient to form a belief as to whether a substantial part of the events giving rise to the Plaintiffs' claims occurred within this judicial district and therefore denies the allegations in this paragraph.

INTRODUCTION

85. Bayer admits that Essure is designed to cause bilateral occlusion of the fallopian tubes, providing permanent birth control. Bayer lacks knowledge or information regarding medical procedures Plaintiffs have undergone and thus denies any such allegations. Bayer also denies all remaining allegations in this paragraph.

86. Bayer lacks knowledge or information regarding Plaintiffs' medical history or their current medical status and thus denies any such allegations. Bayer also denies all remaining allegations in this paragraph.

87. Bayer admits that FDA has granted premarket approval of Essure. Bayer denies that there is a "Conditional Premarket Approval" or "CPMA" status under the law, and Bayer denies all other allegations in this paragraph. Further, this paragraph contains legal conclusions

to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law.

88. Bayer denies that there is "Conditional Premarket Approval" or "CPMA" status under the law, and Bayer denies all other allegations in this paragraph. Further, this paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law.

89. Bayer denies the allegations in this paragraph. Further, this paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law.

90. Bayer denies that there is "Conditional Premarket Approval" or "CPMA" status under the law, and Bayer denies all other allegations in this paragraph. Further, this paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law.

91. This paragraph contains characterizations of regulatory documents which speak for themselves, as well as legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies that Plaintiffs' characterization of the regulatory documents is accurate, and denies the allegations in this paragraph.

92. This paragraph contains characterizations of regulatory documents, which speak for themselves, as well as legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies that Plaintiffs' characterization of the regulatory documents is accurate, and denies the allegations in this paragraph.

93. This paragraph contains characterizations of regulatory documents, which speak for themselves, as well as legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies that Plaintiffs' characterization of the regulatory documents is accurate, and denies the allegations in this paragraph.

94. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

95. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

96. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

97. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

98. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

99. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

100. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

DESCRIPTION OF ESSURE® AND HOW IT WORKS

101. Bayer admits that Essure is an FDA-approved Class III medical device indicated for women who desire permanent birth control by bilateral occlusion of the fallopian tubes.

Bayer denies any and all remaining or inconsistent allegations in this paragraph.

102. Bayer admits that the Essure system is comprised of a disposable delivery system and a wound-down insert, and that a disposable introducer is also provided to facilitate delivery system entry into the hysteroscope operating channel. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

103. Bayer admits that the Essure system insert consists of a super-elastic Nitinol outer coil and a stainless steel inner coil wrapped in polyethylene terephthalate (PET) fibers, and that one flexible Essure insert is placed in the proximal portion of each fallopian tube lumen using a hysteroscope. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

104. Bayer admits that a third party manufactured any hysteroscopic equipment, that hysteroscopic equipment is not part of Essure's PMA order, and that the equipment is not part of Essure. Bayer lacks sufficient knowledge or information regarding the origin of the hysteroscopic equipment used by Plaintiffs' physicians and therefore denies those allegations. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

105. Bayer admits that the Essure system insert consists of a Nitinol outer coil and a stainless steel inner coil wrapped in PET fibers. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

106. Bayer admits that the disposable delivery system consists of a delivery wire, a release catheter, a delivery catheter, and a delivery handle, and that this paragraph purports to depict the disposable delivery system. Bayer also admits that the wound-down insert is attached

to a delivery wire and sheathed by a flexible delivery catheter, and that under hysteroscopy visualization, the Essure inserts are delivered by a physician to the proximal section of the fallopian tube utilizing the delivery system. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

107. Bayer admits that one flexible Essure insert is placed in the proximal portion of each fallopian tube lumen, and that the insert expands upon release to conform to and acutely anchors in the lumen of the fallopian tube. Bayer also admits that the insert elicits a benign tissue in-growth that permanently occludes the fallopian tube, resulting in contraception. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

108. Bayer admits that Essure is an FDA-approved Class III medical device indicated for women who desire permanent birth control by bilateral occlusion of the fallopian tubes. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

109. Bayer admits that the Essure Confirmation Test—either a modified hysterosalpingogram (“HSG”) or transvaginal ultrasound (“TVU”)—is performed three months post-placement to evaluate insert location and fallopian tube occlusion, and that a patient should not rely on Essure inserts for contraception until an Essure Confirmation Test demonstrates bilateral tubal occlusion and satisfactory location of inserts. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

110. Bayer lacks sufficient knowledge or information regarding when or where it allegedly “warrant[ed]” for what Essure does or does not allow. Bayer thus denies the allegations in this paragraph.

111. Bayer denies the allegations in this paragraph.

EVOLUTION OF ESSURE®

112. Bayer admits the allegations in this paragraph.

113. Bayer admits that Conceptus, Inc. became a wholly owned subsidiary of Bayer HealthCare LLC in 2013. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

114. Bayer denies the allegations in this paragraph.

115. Bayer admits that Bayer HealthCare Pharmaceuticals Inc. is the entity primarily engaged in the marketing, sales, and distribution of Essure, among other matters. Bayer denies all remaining or inconsistent allegations in this paragraph.

116. Bayer admits that it trained physicians in conformance with all applicable FDA requirements. It denies all other allegations in this paragraph.

117. Bayer admits that Essure was first manufactured and sold by Conceptus and that Conceptus applied for and received Pre-Market Approval (PMA) for Essure. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

118. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer admits that this paragraph purports to describe the PMA process, but denies that such description is accurate and complete.

119. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer admits that FDA determines whether to grant a PMA application, but denies that Plaintiffs' description of approval is accurate and complete. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

120. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer admits that this paragraph purports to describe the PMA process, but denies that such description is accurate and complete.

121. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer admits that it is not uncommon for FDA to spend more than 1,000 hours reviewing a PMA application, but lacks sufficient knowledge or information regarding Plaintiffs' contentions related to the agency's practices. It therefore denies any and all remaining or inconsistent allegations in this paragraph.

122. Bayer denies the allegations in this paragraph.

123. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer admits that the allegations in this paragraph purport to describe legal requirements under the cited statute and regulation, but denies that the descriptions in this paragraph are accurate and complete, and further states that the cited statute and regulation speak for themselves. Bayer denies any and all allegations remaining or inconsistent allegations in this paragraph.

124. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies that devices are "conditionally approved" or that there is such a status under the law. Bayer likewise denies any and all remaining or inconsistent allegations in this paragraph.

125. Bayer denies that Essure is "conditionally approved" or that there is such a status under the law. Bayer likewise denies any and all remaining or inconsistent allegations in this paragraph.

126. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer admits that the allegations in this paragraph purport to describe the FDA's Approval Order regarding Essure, but denies that this paragraph accurately or completely describes the Approval Order, which speaks for itself. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

REQUIREMENTS UNDER FEDERAL REGULATIONS

127. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer admits that the allegations in this paragraph purport to describe federal regulations and the FDA's Approval Order regarding Essure, but denies that this paragraph accurately or completely describes the Approval Order or the cited federal regulations, which speak for themselves. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

128. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer admits that the allegations in this paragraph purport to describe legal requirements under the cited regulations, but denies that the descriptions in this paragraph are accurate and complete, and further states that the cited regulations speak for themselves. Bayer denies any and all allegations remaining or inconsistent allegations in this paragraph.

129. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer admits that the allegations in this paragraph purport to describe legal requirements under the cited regulations, but deny that the descriptions in this paragraph are accurate and complete, and further states that the cited regulations speak for

themselves. Bayer denies any and all allegations remaining or inconsistent allegations in this paragraph.

FAILURES OF DEVICE

130. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

VIOLATIONS OF FEDERAL REQUIREMENTS

131. Bayer admits that, in June and July 2002, prior to Essure approval, FDA inspectors conducted an inspection of a Conceptus manufacturing facility, but denies that the descriptions of the FDA observations are accurate or complete. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

132. Bayer admits that, in June and July 2002, prior to Essure approval, FDA inspectors conducted an inspection of a Conceptus manufacturing facility, but denies that the descriptions of the FDA observations are accurate or complete. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

133. Bayer admits that, in June and July of 2003, FDA inspectors conducted an inspection of a Conceptus manufacturing facility. Bayer also admits that the allegations in this paragraph purport to describe a Form 483 related to that inspection, but Bayer denies that more than one Form 483 was issued and further denies that the descriptions in this paragraph are accurate and complete. Bayer denies any and all remaining allegations in this paragraph.

134. Bayer denies the allegations in this paragraph.

135. Bayer admits that the allegations in this paragraph purport to describe FDA observations from an inspection conducted in December 2010 and January 2011, but denies that

the allegations in this paragraph accurately or completely describe the observations. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

136. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

137. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

138. Bayer admits that the allegations in this paragraph purport to describe FDA observations in Form 483s issued on July 7, 2003 and January 6, 2011, but denies that the descriptions of these observations are accurate and complete. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

139. Bayer lacks sufficient knowledge or information to judge whether it "admitted" the statement Plaintiffs allege that it did because Plaintiffs have failed to allege when, where, or to whom the statement was made. Accordingly, Bayer denies any and all allegations in this paragraph.

140. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

141. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

FDA HEARINGS AND RESULTING ACTION

142. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

143. Bayer denies the allegations in this paragraph.

144. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer admits that FDA convened a public hearing regarding Essure in September 2015, but denies any and all remaining or inconsistent allegations in this paragraph.

145. Bayer admits that FDA provided preliminary guidance for comment on February 29, 2016. Bayer denies that Plaintiffs' characterization provides an accurate and complete description of that guidance, which speaks for itself. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

146. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

147. Bayer denies the allegations in this paragraph.

148. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

DEFENDANT'S TRAINING AND DISTRIBUTION PLAN

149. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

150. Bayer admits that it trained physicians in accordance with all applicable FDA requirements but denies all other allegations in this paragraph.

151. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

152. Bayer lacks sufficient knowledge or information to judge whether it made the statement Plaintiffs allege that it did because Plaintiffs have failed to allege when, where, or to whom the statement was made. Accordingly, Bayer denies any and all allegations in this paragraph.

153. Bayer admits that it trained physicians in accordance with all applicable FDA requirements but denies all other allegations in this paragraph.

154. Bayer admits that it trained physicians in accordance with all applicable FDA requirements but denies all other allegations in this paragraph. Further, Bayer states that FDA did not require training regarding Essure removal.

155. Bayer admits that it trained physicians in accordance with all applicable FDA requirements but denies all other allegations in this paragraph.

156. Bayer lacks sufficient knowledge or information regarding the origin of the hysteroscopic equipment used by Plaintiffs' physicians and therefore denies those allegations. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

157. Plaintiffs' allegations are vague as to purported agreements, and Bayer therefore denies those allegations. Bayer further denies any and all remaining or inconsistent allegations in this paragraph.

158. Plaintiffs' allegations are vague as to purported agreements, and Bayer lacks knowledge or information sufficient to form a belief as to the truth or falsity of these allegations. Bayer therefore denies the allegations in this paragraph.

159. Bayer lacks sufficient knowledge or information to judge whether it made the statement Plaintiffs allege that it did because Plaintiffs have failed to allege when the statement

was made in a purported 10Q report. Accordingly, Bayer denies any and all allegations in this paragraph.

160. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

161. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

162. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

163. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

164. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

165. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

166. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

167. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

168. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

PLAINTIFFS' HISTORIES

169. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

170. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

171. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

172. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

173. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

174. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

175. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

176. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

177. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

178. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

179. This Plaintiff has voluntarily dismissed her claims against Bayer, and as a result, no response is required. To the extent that a response is necessary, Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

180. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

181. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

182. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

183. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

184. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

185. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

186. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

187. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

188. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

189. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

190. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

191. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

192. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

193. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

194. This Plaintiff has voluntarily dismissed her claims against Bayer, and as a result, no response is required. To the extent that a response is necessary, Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

195. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

196. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

197. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

198. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

199. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

200. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

201. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

202. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

203. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

204. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

205. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

206. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

207. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

208. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

209. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

210. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

211. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

212. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

213. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

214. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

215. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

216. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

217. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

218. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

219. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

220. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

221. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

222. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

223. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

224. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

225. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

226. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

227. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

228. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

229. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

230. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

231. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

232. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

233. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

234. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

235. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

236. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

237. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

238. Bayer lacks sufficient knowledge or information to form a belief as to this Plaintiff's residency, date that she had Essure placed, or her medical history. Bayer therefore denies the allegations in this paragraph.

FRAUDULENT CONCEALMENT/DISCOVERY RULE/EQUITABLE

TOLLING/EQUITABLE ESTOPPEL

SUMMARY OF ACTIVE CONCEALMENT

239. The allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

240. The allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

241. The allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

242. The allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

243. The allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

244. The allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

245. The allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

246. Bayer denies the allegations in this paragraph.

247. The allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

FDA CALLS ESSURE® MEETING

248. Bayer admits that FDA convened a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee on September 24, 2015. Bayer denies that Plaintiffs' description of the meeting is accurate or complete, and Bayer denies all remaining or inconsistent allegations in this paragraph.

249. Bayer admits that on February 29, 2016, FDA released preliminary guidance regarding the Essure labeling, including a Patient Decision Checklist. Bayer denies that Plaintiffs' allegations are an accurate and complete description of the guidance, which speaks for itself, and Bayer denies any and all remaining or inconsistent allegations in this paragraph.

250. Bayer denies that Plaintiffs' description of FDA's actions is accurate and complete, and denies all allegations in this paragraph.

251. Bayer denies the allegations in this paragraph.

252. Bayer admits that the Patient Decision Checklist contains spaces for patients to place their initials. Bayer denies that Plaintiffs' description of the checklist, which speaks for itself, is accurate or complete, and Bayer denies all remaining or inconsistent allegations in this paragraph.

253. Bayer admits that women considering obtaining Essure will be fully informed of any risks, but denies that such women were not informed of the risks prior to the inclusion of the Patient Decision Checklist. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

254. Bayer denies the allegations in this paragraph.

255. Bayer denies the allegations in this paragraph.

256. Bayer admits that the checklist discloses a risk of migration and perforation, and further states that the FDA labeling disclosed those risks before the FDA released its proposed guidance. Bayer denies all remaining or inconsistent allegations in this paragraph.

257. Bayer denies the allegations in this paragraph.

258. Bayer denies the allegations in this paragraph.

259. Bayer admits that FDA's February 29, 2016 guidance proposed a boxed warning, but it denies that Plaintiffs' description of this boxed warning, which speaks for itself, is accurate or complete. Bayer denies all remaining or inconsistent allegations in this paragraph.

260. Bayer admits that FDA's February 29, 2016 guidance, which speaks for itself, proposed a black-box warning. FDA released final guidance in October 2016, which supersedes this proposed guidance.

261. Bayer denies the allegations in this paragraph.

DISCOVERY RULE – TOLLING

262. Bayer denies that Plaintiffs lacked knowledge of the claims and allegations asserted in the amended complaint until February 29, 2016. Moreover, this paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies these allegations.

263. Bayer denies the allegations in this paragraph.

264. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

265. Bayer denies the allegations in this paragraph.

266. Bayer lacks sufficient knowledge or information to form a belief regarding the allegations in this paragraph concerning Plaintiffs' alleged investigations and conversations, and therefore denies the allegations in this paragraph.

267. Bayer denies that its conduct was the cause of any alleged injuries. The remaining allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations.

268. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer lacks sufficient knowledge or information to form a belief regarding the allegations in this paragraph concerning Plaintiffs' alleged suspicious or knowledge, and therefore denies the allegations in this paragraph.

269. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

270. Plaintiffs state a legal conclusion, which does not require a response. To the extent a response is required, Bayer denies the allegations in this paragraph.

FRAUDULENT CONCEALMENT – EQUITABLE TOLLING

271. The allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

272. The allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

273. The allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

274. The allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

275. The allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

276. The allegations in this paragraph contain legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

EQUITABLE ESTOPPEL

277. Plaintiffs state a legal conclusion, which does not require a response. To the extent a response is required, Bayer denies the allegations in this paragraph.

278. Bayer denies the allegations in this paragraph.

279. Bayer denies the allegations in this paragraph.

280. Plaintiffs state a legal conclusion, which does not require a response. To the extent a response is required, Bayer denies the allegations in this paragraph.

FACTS AND WARRANTIES

281. Bayer denies the allegations in this paragraph.

282. Bayer lacks sufficient knowledge or information to form a belief regarding the allegations in this paragraph. It therefore denies the allegations in this paragraph.

283. Bayer admits that it followed all applicable FDA requirements, and that it created a Physician Training Manual and simulator. It denies any and all remaining or inconsistent allegations in this paragraph, including that it trained physicians in hysteroscopy.

284. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

285. Bayer denies the allegations in this paragraph.

286. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

287. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

288. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

289. Bayer lacks sufficient knowledge or information to form a belief regarding what Plaintiffs relied on, and therefore denies all allegations regarding the same. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

NEGLIGENT TRAINING – COUNT I

290. The cross-reference in this paragraph does not require a response.

291. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies the allegations in this paragraph.

292. Bayer admits that it has complied with all applicable FDA training requirements. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

293. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer admits that it has a duty to comply with FDA requirements, and further states that it did so. Bayer denies any and all remaining or inconsistent

allegations in this paragraph, including allegations which relate to matters dismissed in this Court's prior rulings as preempted by federal law.

294. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer admits that it has a duty to comply with FDA requirements, and further states that it did so. Bayer denies that Plaintiffs' characterization of these requirements are accurate. Bayer denies any and all remaining or inconsistent allegations in this paragraph, including all subparts.

295. Plaintiffs fail to specify the provenance of the goals alleged in the subparts. Bayer accordingly lacks sufficient information or knowledge to form a belief regarding the allegations in this paragraph, and therefore denies the same, including all subparts.

296. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph, including all subparts. Bayer denies that Plaintiffs' characterization of FDA requirements is accurate.

297. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph, including all subparts. Bayer denies that Plaintiffs' characterization of FDA requirements is accurate.

298. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies that its conduct caused any injury to Plaintiff. And therefore denies the remaining allegations in this paragraph.

299. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

300. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

301. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

302. Bayer lacks sufficient information or knowledge regarding Plaintiffs' medical history, and therefore denies the allegations in this paragraph.

303. Bayer lacks sufficient information or knowledge regarding Plaintiffs' medical history or financial condition, and therefore denies the allegations in this paragraph.

WHEREFORE, Bayer denies that Plaintiffs are entitled to judgment on Count I of the Complaint.

NEGLIGENCE – RISK MANAGEMENT – COUNT II

304. This cross-reference does not require a response.

305. This paragraph contains legal conclusions to which no response is required, and characterizations of federal regulations, which speak for themselves. To the extent any response is required, Bayer admits that it complied with FDA requirements. Bayer denies any and all remaining or inconsistent allegations in this paragraph, including all subparts, and denies that Plaintiffs' characterization of federal regulations is accurate.

306. This paragraph contains legal conclusions to which no response is required, and characterizations of federal regulations, which speak for themselves. To the extent any response is required, Bayer admits that it was subject to certain FDA regulations but denies that it violated such regulations and denies the allegations in this paragraph, including all subparts. Bayer denies that Plaintiffs' characterization of federal regulations is accurate.

307. Bayer denies the allegations in this paragraph.

308. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Bayer denies the allegations in this paragraph.

309. This paragraph contains legal conclusions to which no response is required, and which relate to matters dismissed in this Court's prior rulings as preempted by federal law. To the extent a response is required, Bayer denies that its conduct caused any injury to Plaintiffs. Bayer also lacks sufficient information or knowledge regarding Plaintiffs' medical history, and therefore denies allegations regarding the same. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

310. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies that its conduct caused any injury to Plaintiffs. Bayer also lacks sufficient information or knowledge regarding Plaintiffs' medical history, and therefore denies the remaining allegations in this paragraph.

311. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies that its conduct caused any injury to Plaintiffs. Bayer also lacks sufficient information or knowledge regarding Plaintiffs' medical history, and therefore denies the remaining allegations in this paragraph.

312. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies that its conduct caused any injury to Plaintiffs. Bayer also lacks sufficient information or knowledge regarding Plaintiffs' medical history, and therefore denies the remaining allegations in this paragraph.

313. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies that its conduct caused any injury to Plaintiffs. Bayer also lacks sufficient information or knowledge regarding Plaintiffs' medical history, and therefore denies the remaining allegations in this paragraph.

314. Bayer lacks sufficient information or knowledge regarding Plaintiffs’ medical history or financial conditions, and therefore denies the allegations in this paragraph.

315. Bayer lacks sufficient information or knowledge regarding Plaintiffs’ medical history or financial conditions, and therefore denies the allegations in this paragraph.

WHEREFORE, Bayer denies that Plaintiffs are entitled to judgment on Count II of the Complaint.

BREACH OF EXPRESS WARRANTY– COUNT III

316. This cross-reference does not require a response.

317. Bayer admits that the Approval Order for Essure states that FDA’s Center for Devices and Radiological Health “does not evaluate information related to contract liability warranties, [but Bayer] should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.” Bayer denies any and all remaining or inconsistent allegations in this paragraph.

318. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies that its conduct caused any injury to Plaintiffs, and it denies that any express warranties “were specifically negotiated and expressly communicated to Plaintiffs” by Bayer. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

319. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer admits that FDA approved substantially similar statements to those recited, and denies that it made statements inconsistent with FDA-approved labeling. Bayer denies that any of the statements alleged in this paragraph “created the basis of [a] bargain.” Further, Bayer lacks sufficient information and knowledge regarding whether

Plaintiffs saw or relied on the alleged statements, and therefore denies these allegations. Bayer also denies that any statements alleged in this paragraph that were made by Bayer were false. Bayer denies any and all remaining or inconsistent allegations in this paragraph, including subparts.

320. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

321. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

322. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

323. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer lacks sufficient information or knowledge regarding Plaintiffs' medical history, and therefore denies the allegations in this paragraph regarding the same. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

324. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer lacks sufficient information or knowledge regarding Plaintiffs' medical history, and therefore denies the allegations in this paragraph regarding the same. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

325. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer lacks sufficient information or knowledge regarding Plaintiffs' medical history, and therefore denies the allegations in this paragraph regarding the same. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

326. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer lacks sufficient information or knowledge regarding Plaintiffs' medical history, and therefore denies the allegations in this paragraph regarding the same. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

327. Bayer lacks sufficient information or knowledge regarding Plaintiffs' medical history and financial condition, and therefore denies the allegations in this paragraph regarding the same. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

328. Bayer lacks sufficient information or knowledge regarding Plaintiffs' medical history and financial condition, and therefore denies the allegations in this paragraph.

WHEREFORE, Bayer denies that Plaintiffs are entitled to judgment on Count III of the Complaint.

NEGLIGENT MISREPRESENTATION – COUNT IV

329. This cross-reference does not require a response.

330. First, the Court has already dismissed claims based on the allegations in subparts (a) through (j), (m) through (p), and (r) through (t), and thus no response is required. Second, this paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies that any of the statements alleged in this paragraph “created the basis of [a] bargain.” Finally, Bayer lacks sufficient information and knowledge regarding whether Plaintiffs saw or relied on the alleged statements, and therefore denies these allegations. Bayer also denies that any statements alleged in this paragraph that were made by Bayer were false. Bayer denies any and all remaining or inconsistent allegations in this paragraph, including subparts.

331. This paragraph states a legal conclusion, which does not require a response. To the extent that a response is required, Bayer denies the allegations in this paragraph.

332. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer denies the allegations in this paragraph.

333. This paragraph states a legal conclusion, which does not require a response. To the extent that a response is required, Bayer denies the allegations in this paragraph.

334. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer lacks sufficient information or knowledge regarding Plaintiffs' medical history, and therefore denies the allegations in this paragraph regarding the same. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

335. This paragraph states a legal conclusion, which does not require a response. To the extent that a response is required, Bayer denies the allegations in this paragraph.

336. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer lacks sufficient information or knowledge regarding Plaintiffs' medical history, and therefore denies the allegations in this paragraph regarding the same. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

337. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer lacks sufficient information or knowledge regarding Plaintiffs' medical history and financial condition, and therefore denies the allegations in this paragraph regarding the same. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

338. This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Bayer lacks sufficient information or knowledge regarding

Plaintiffs' medical history, and therefore denies the allegations in this paragraph regarding the same. Bayer denies any and all remaining or inconsistent allegations in this paragraph.

WHEREFORE, Bayer denies that Plaintiffs are entitled to judgment on Count IV of the Complaint.

NEGLIGENCE – FAILURE TO WARN – COUNT V

339. This cross-reference does not require a response.

340. This paragraph states a legal conclusion, which does not require a response. To the extent that a response is required, Bayer denies the allegations in this paragraph.

341. This paragraph contains legal conclusions to which no response is required, and characterizations of federal regulations, which speak for themselves. To the extent any response is required, Bayer admits that it has a duty to comply with certain FDA requirements and further states that it satisfied that duty. Bayer denies all remaining or inconsistent allegations in this paragraph, including all subparts, and denies that Plaintiffs' characterization of FDA requirements is accurate.

342. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Bayer denies the allegations in this paragraph, including all subparts.

343. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Bayer denies the allegations in this paragraph.

344. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Bayer denies the allegations in this paragraph.

345. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Bayer denies that its conduct caused any injury to Plaintiffs.

Bayer also lacks sufficient information or knowledge regarding Plaintiffs' medical history, and therefore denies the remaining allegations in this paragraph.

346. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Bayer denies that its conduct caused any injury to Plaintiffs. Bayer also lacks sufficient information or knowledge regarding Plaintiffs' medical history, and therefore denies the remaining allegations in this paragraph.

347. This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Bayer denies that its conduct caused any injury to Plaintiffs. Bayer also lacks sufficient information or knowledge regarding Plaintiffs' medical history, and therefore denies the remaining allegations in this paragraph.

348. Bayer lacks sufficient information or knowledge regarding Plaintiffs' medical history or financial condition, and therefore denies the allegations in this paragraph.

349. Bayer lacks sufficient information or knowledge regarding Plaintiffs' medical history or financial condition, and therefore denies the allegations in this paragraph.

WHEREFORE, Bayer denies that Plaintiffs are entitled to judgment on Count V of the Complaint.

SEPARATE OR AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that one or more of the following defenses should be available to Bayer in this matter. Bayer accordingly asserts these defenses. Upon completion of discovery, if the facts warrant, Bayer may withdraw any of these defenses as may be appropriate. By setting forth these defenses, Bayer does not assume the burden of proving any fact, issue, or element of a cause of action where such burden properly belongs to Plaintiffs. Moreover, nothing stated herein is intended or shall be construed as an acknowledgment that any particular issue or

subject necessarily is relevant to Plaintiffs' allegations. Bayer further reserves the right to amend its Answer and to assert additional defenses and other claims, as this matter proceeds.

Further answering, by way of additional defenses, Bayer states as follows:

1. Plaintiffs' Complaint, and each and every count therein, fails to state a cause of action or claim upon which relief can be granted.

2. Plaintiffs' claims are expressly preempted by federal law, including the express preemption provision of the Medical Device Amendments, 21 U.S.C. § 360k(a), to the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* Plaintiffs' claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

3. Plaintiffs' claims are impliedly preempted by federal law. *See* 21 U.S.C. § 337; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

4. At all relevant times, the Essure System was in full compliance with all applicable federal statutes and regulations, including but not limited to the Medical Device Amendments, 21 U.S.C. § 360c, *et seq.*, to the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, and other federal statutes and regulations, and Plaintiffs' claims are accordingly barred.

5. To the extent that Plaintiffs' claims are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

6. Plaintiffs cannot state a claim upon which relief may be granted with regard to injuries allegedly caused by an FDA-approved medical device because the remedy sought by Plaintiffs are subject to the exclusive regulation of the FDA. *See* 21 U.S.C. § 337; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

7. This Court should abstain from adjudicating Plaintiffs' claims relating to injuries allegedly caused by an FDA-approved medical device in deference to the interpretation of regulations relating to medical devices by the FDA.

8. Plaintiffs' claims regarding injuries allegedly caused by an FDA-approved medical device are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with regulating medical devices including the Essure System.

9. To the extent Plaintiffs' claims are related to Bayer's advertising, public statements, or other activities protected by the First Amendment of the Constitution of the United States or by the constitutions of any applicable state, such claims are barred.

10. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations or statutes of repose.

11. Plaintiffs' claims are barred, in whole or in part, by laches, waiver, or estoppel.

12. Plaintiffs' claims are barred, in whole or in part, by Plaintiffs' failure to mitigate Plaintiffs' alleged damages.

13. The acts and omissions of Plaintiffs caused or contributed to the alleged damages, thereby barring or reducing the amount of recovery under the doctrines of contributory negligence or comparative negligence. Plaintiffs' recovery, if any, therefore is barred or should be apportioned in accordance with applicable law.

14. The alleged injuries sustained by Plaintiffs, if any, were caused, in whole or in part, by pre-existing physical, medical, or physiological conditions, for which Bayer has no legal responsibility.

15. If Plaintiffs suffered injuries as alleged in the Complaint, which is expressly denied, such injuries arose from, and were caused by, risks, hazards, and dangers knowingly

assumed by Plaintiffs. Plaintiffs' recovery accordingly is barred or should be reduced by Plaintiffs' assumption of the risk.

16. If the injuries claimed by Plaintiffs were related to the use of Essure, which is expressly denied, any such injuries were the result of an idiosyncratic or allergic reaction to Essure.

17. The injuries and damages claimed by Plaintiffs, if any, resulted from an intervening or superseding cause or causes, and any act or omission on the part of Bayer was not the proximate or competent producing cause of such alleged injuries and damages.

18. The injuries and damages claimed by Plaintiffs, if any, are barred or must be reduced because those damages arose from the acts or omissions of persons or entities other than Bayer for whom Bayer has no legal responsibility.

19. If Plaintiffs sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse, or use inconsistent with the labeling of the FDA-approved medical device Essure, or by use inconsistent with the training provided for the insertion of Essure inserts. Plaintiffs' recovery is accordingly barred.

20. If Plaintiffs sustained the injuries or incurred the expenses as alleged, which is expressly denied, the conduct of independent third parties was the sole cause of any alleged damages or injuries that Plaintiffs may have sustained. Consequently, no act or omission of Bayer was the proximate cause of Plaintiffs' alleged damages or injuries, thereby prohibiting the imposition of liability on Bayer.

21. The alleged injuries and damages, if any, were the result of unavoidable circumstances that could not have been prevented by any person, including Bayer.

22. There was no causal connection between any alleged defect in the product at issue and Plaintiffs' alleged damages with the result that Plaintiffs are not entitled to recover against Bayer in this action.

23. Plaintiffs' claims are barred because Bayer did not owe a legal duty to Plaintiffs. If Bayer owed Plaintiffs a legal duty, it did not breach that duty.

24. The claims in the Complaint are barred in whole or in part by the learned intermediary and informed intermediary doctrines.

25. Plaintiffs' Complaint fails to state a claim upon which relief can be granted in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing, promotion and sale of Essure®, including but not limited to adequate warnings and instructions with respect to the product's use included in the product's instructions and other literature, conformed to the applicable state of the art. Essure, including its labeling approved by the FDA, complied with the state of scientific and medical knowledge available at the time. Plaintiffs' recovery accordingly is barred.

26. The warnings and instructions accompanying Essure at the time of the occurrence or injuries alleged by Plaintiffs were legally adequate warnings and instructions.

27. Bayer gives notice that to the extent the sophisticated purchaser doctrine is applicable to any of the allegation in the Complaint, Bayer intends to rely upon same in defense of this action.

28. Plaintiffs' claims are barred in whole or in part because the commercial speech relating to Essure is protected under the First Amendment of the United States Constitution and the applicable state constitution.

29. Plaintiffs did not detrimentally rely on any labeling, warnings, or information

concerning Essure.

30. Bayer did not make any misrepresentations of fact material to Plaintiffs' treatment with Essure.

31. Plaintiffs' alleged reliance, if any, on alleged misrepresentations, omissions or concealment by Bayer, which is categorically denied, was not reasonable and did not cause any of the damages alleged by Plaintiffs.

32. Plaintiffs' prescribing physicians did not rely on any representations by Bayer—in addition to the FDA-approved labeling—in treating Plaintiff.

33. Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part by collateral sources.

34. To the extent that Plaintiffs' Complaint seeks recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under applicable law.

35. To the extent that Plaintiffs' claims have been settled or Plaintiffs will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of Bayer, if any, should be reduced accordingly.

36. Plaintiffs' claims may be barred, in whole or in part, due to res judicata, collateral estoppel, or by release of claims.

37. Plaintiffs' Complaint fails to state a claim upon which relief can be granted as to costs, attorneys' fees, or delay damages.

38. Plaintiffs' Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

39. Plaintiffs' Complaint fails to state a claim for fraud, and fails to allege the circumstances constituting fraud with the particularity required by the applicable Rules of Civil Procedure.

40. Plaintiffs' claims for breach of warranty are barred because Plaintiffs failed to give timely notice of any alleged breach of warranty.

41. Bayer did not sell or distribute Essure to Plaintiffs, and Plaintiffs did not receive or rely upon any representations or warranties as alleged in the Complaint. Plaintiffs' claims for breach of warranty are barred by lack of privity between Plaintiffs and Bayer.

42. Plaintiffs' claims for breach of warranty, express or implied, are barred by the applicable state's Uniform Commercial Code or other applicable law.

43. Venue may be improper.

44. This Court may not be the proper forum, and may be an inconvenient forum, for the just adjudication of Plaintiffs' claims.

45. Plaintiffs' recovery, if any, and Bayer's liability, if any, are subject to the provisions and limitations in the Pennsylvania Fair Share Act, 42 Pa. C.S.A. § 7102.

46. Plaintiffs' claims are barred to the extent that Plaintiffs' conduct was highly reckless and was the sole or superseding cause of the injuries that Plaintiffs allegedly sustained.

47. Plaintiffs' claims are barred pursuant to the Restatement (Second) of Torts, section 402A, comment k.

48. Plaintiffs' claims of product defect, if any, are or may be barred by Section 4 of the Restatement (Third) of Torts: Products Liability, because Essure complied with applicable product safety statutes and administrative regulations.

49. The imposition of punitive damages in this case would violate Bayer's rights to

procedural and substantive due process under the United States Constitution and applicable state constitutional provisions.

50. Plaintiffs' claims for punitive damages cannot be sustained by a jury that (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award for punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation, the residence, wealth, and corporate status of a defendant; (4) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part directly on the basis of injury upon non-parties; (5) is not provided constitutionally adequate procedures to protect against the risk of an award of punitive damages that seeks to punish a defendant for having caused injury to others; (6) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (7) is not properly instructed regarding Plaintiffs' burden of proof with respect to each and every element of a claim for punitive damages; and (8) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards. An award of punitive damages under such circumstances would violate Bayer's due process rights and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the state constitution involved herein, and would be improper under the common law and public policy of

this state.

51. Plaintiffs' Complaint does not contain sufficient allegations to demonstrate that this Court has personal jurisdiction over Plaintiffs' claims. *See BNSF Railway Co. v. Tyrrell*, 137 S. Ct. 1549 (2017); *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County*, 137 S. Ct. 1773 (2017).

52. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

53. Bayer hereby gives notice that it reserves the right to reply on the laws of states other than Pennsylvania to the extent applicable, including without limitation the laws of New Jersey or such other states whose laws might apply, and Bayer asserts any and all applicable defenses under the laws of those states.

WHEREFORE, Bayer requests that Plaintiffs' Complaint be dismissed with prejudice, that judgment be entered in favor of Bayer and against Plaintiffs, and that Bayer be awarded the costs of this action, together with such other and further relief as may be appropriate.

DEMAND FOR JURY TRIAL

Bayer hereby demands a trial by jury on all claims so triable.

PRAYER FOR RELIEF

WHEREFORE, Bayer prays for judgment as follows:

1. That Plaintiffs take nothing by way of the Complaint;
2. That judgment be entered in favor of Bayer and against Plaintiffs and that the Complaint be dismissed with prejudice;
3. That Bayer be awarded its costs of suit incurred in the defense of this action;
4. For a jury trial on all issues so triable; and
5. For such other relief as this Court deems proper.

Dated: March 23, 2017

DECHERT LLP

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CERTIFICATE OF SERVICE

I, Christopher R. Boisvert, hereby certify that on March 23, 2018, the foregoing was filed via the Court's CM/ECF system, which will automatically serve and send notification of such filing to all registered attorneys of record.

/s/ Christopher R. Boisvert